SENATE BILL No. 275

DIGEST OF INTRODUCED BILL

Citations Affected: IC 5-10-8-7.4; IC 27-8-14.3; IC 27-13-7-15.5.

Synopsis: Clinical trials. Defines "associated treatment cost" for purposes of payment for medically necessary treatment and drugs and devices associated with clinical trial treatments. Requires group health benefit plans for public employees, individual and group accident and sickness insurance policies, and individual and group health maintenance organization contracts to provide coverage for associated treatment cost. Prohibits dollar limits, deductibles, copayments, or coinsurance requirements on coverage of associated treatment cost that are less favorable than those for physical illness generally. Requires health benefit plan administrators, insurers, and health maintenance organizations to submit annual reports to the insurance commissioner describing clinical trials for which associated treatment cost was covered. Requires the insurance commissioner to compile information gathered and make an annual report available to the public. Establishes a work group on health care coverage for associated treatment cost to study and make recommendations regarding costs and benefits of the coverage required under this act.

Effective: July 1, 2001.

Gard

January 11, 2001, read first time and referred to Committee on Health and Provider Services.

Introduced

First Regular Session 112th General Assembly (2001)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2000 General Assembly.

SENATE BILL No. 275

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-7.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 7.4. (a) As used in this chapter, "administrator" means:**

(1) the state personnel department;

(2) an entity with which the state contracts to administer health coverage under section 7(b) of this chapter; or

(3) a prepaid health care delivery plan with which the state contracts under section 7(c) of this chapter.

(b) As used in this section, "associated treatment cost" means the cost of a medically necessary treatment associated with clinical trial treatment. The term does not include:

(1) the cost of an investigational drug or device used as part of the clinical trial treatment;

(2) the cost of nonhealth care services associated with the clinical trial treatment;

(3) the cost of managing the research associated with the

clinical trial treatment; or

(4) a cost not covered under the health benefit plan for noninvestigational treatments.

(c) As used in this section, "clinical trial treatment" means:

(1) treatment provided in a phase II, phase III, or phase IV clinical trial for a life threatening condition;

(2) prevention studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer;

(3) early detection studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer; or

(4) treatment studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer;

that is approved by the National Institutes of Health or one (1) of its cooperative groups or centers, the federal Food and Drug Administration in the form of an investigational new drug application, the United States Department of Veterans Affairs, or an institutional review board of an institution in Indiana that has a multiple project assurance contract approved by the office of protection from research risks of the National Institutes of Health.

(d) As used in this section, "cooperative group" means a formal network of facilities that collaborate on research projects and have an established peer review program operating within the group that is approved by the National Institutes of Health. The term includes:

(1) the National Cancer Institute Clinical Cooperative Group;

(2) the National Cancer Institute Community Clinical Oncology Program;

(3) the AIDS Clinical Trials Group; and

(4) the Community Programs for Clinical Research in AIDS.

(e) As used in this section, "covered individual" means an individual who is:

(1) covered under a self-insurance program established under section 7(b) of this chapter to provide group health coverage; or

(2) entitled to services under a contract for health services entered into or renewed under section 7(c) of this chapter.

(f) As used in this chapter, "health benefit plan" means:

(1) a self-insurance program established under section 7(b) of this chapter to provide group health coverage; or

(2) a contract for health services entered into or renewed under section 7(c) of this chapter.

(g) As used in this section, "multiple project assurance

contract" means a contract between an institution and the United States Department of Health and Human Services that defines the relationship between the institution and the United States Department of Health and Human Services and specifies the responsibilities of the institution and procedures that will be used by the institution to protect human research subjects.

(h) A health benefit plan must provide a covered individual with coverage for associated treatment cost if:

(1) the facility and personnel providing the clinical trial treatment are approved by the organization sponsoring the clinical trial protocol and the institutional review board of the institution providing the clinical trial treatment;

(2) there is no clearly superior, noninvestigational treatment alternative to the clinical trial treatment; and

(3) the available clinical or preclinical data provide a reasonable expectation that the clinical trial treatment will be at least as effective as a noninvestigational alternative.

(i) The coverage required under subsection (h) includes associated treatment cost for a drug or device approved for sale by the federal Food and Drug Administration to the extent that the manufacturer, distributor, or provider of the drug or device does not pay the cost, regardless of whether the drug or device is approved for the covered individual's particular condition.

(j) The coverage required under subsections (h) and (i) may not be subject to dollar limits, deductibles, copayments, or coinsurance provisions that are less favorable to a covered individual than the dollar limits, deductibles, copayments, or coinsurance provisions applying to physical illness generally under the health benefit plan.

(k) On or before June 1 of each year, each administrator shall submit to the insurance commissioner, on a form approved by the insurance commissioner, a report describing clinical trials for which the health benefit plan covered associated treatment cost during the prior year.

(l) The insurance commissioner shall compile an annual summary report of the information submitted under subsection (k) and make copies available to the public.

(m) The insurance commissioner shall adopt rules under IC 4-22-2 to implement subsections (k) and (l).

SECTION 2. IC 27-8-14.3 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]:

Chapter 14.3. Coverage Associated With Clinical Trials

Sec. 1. (a) As used in this chapter, "accident and sickness insurance policy" means an insurance policy that:

(1) provides one (1) or more of the types of insurance described in IC 27-1-5-1, classes 1(b) and 2(a); and

(2) is issued on an individual or group basis.

(b) As used in this chapter, "associated treatment cost" means the cost of a medically necessary treatment associated with clinical trial treatment. The term does not include:

(1) the cost of an investigational drug or device used as part of the clinical trial treatment;

(2) the cost of nonhealth care services associated with the clinical trial treatment;

(3) the cost of managing the research associated with the clinical trial treatment; or

(4) a cost not covered under the accident and sickness insurance policy for noninvestigational treatments.

(c) As used in this chapter, "clinical trial treatment" means:

(1) treatment provided in a phase II, phase III, or phase IV clinical trial for a life threatening condition;

(2) prevention studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer;

(3) early detection studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer; or

(4) treatment studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer;

that is approved by the National Institutes of Health or one (1) of its cooperative groups or centers, the federal Food and Drug Administration in the form of an investigational new drug application, the United States Department of Veterans Affairs, or an institutional review board of an institution in Indiana that has a multiple project assurance contract approved by the office of protection from research risks of the National Institutes of Health.

(d) As used in this chapter, "cooperative group" means a formal network of facilities that collaborate on research projects and have an established peer review program operating within the group that is approved by the National Institutes of Health. The term includes:

(1) the National Cancer Institute Clinical Cooperative Group;

(2) the National Cancer Institute Community Clinical Oncology Program;

(3) the Aids Clinical Trials Group; and

(4) the community programs for clinical research in AIDS.

(e) As used in this chapter, "insured" means an individual who is entitled to coverage under an accident and sickness insurance policy that the insurer issues in Indiana.

(f) As used in this chapter, "multiple project assurance contract" means a contract between an institution and the United States Department of Health and Human Services that defines the relationship between the institution and the United States Department of Health and Human Services and specifies the responsibilities of the institution and procedures that will be used by the institution to protect human research subjects.

Sec. 2. (a) An insurer must provide coverage for associated treatment cost in an accident and sickness insurance policy that the insurer issues in Indiana if:

(1) the facility and personnel providing the clinical trial treatment are approved by the organization sponsoring the clinical trial protocol and the institutional review board of the institution providing the clinical trial treatment;

(2) there is no clearly superior, noninvestigational treatment alternative to the clinical trial treatment; and

(3) the available clinical or preclinical data provide a reasonable expectation that the clinical trial treatment will be at least as effective as a noninvestigational alternative.

(b) The coverage required under subsection (a) includes associated treatment cost for a drug or device approved for sale by the federal Food and Drug Administration to the extent that the manufacturer, distributor, or provider of the drug or device does not pay the cost, regardless of whether the drug or device is approved for the insured's particular condition.

(c) The coverage required under this chapter may not be subject to dollar limits, deductibles, or coinsurance provisions that are less favorable to an insured than the dollar limits, deductibles, or coinsurance provisions applying to physical illness generally under the accident and sickness insurance policy.

Sec. 3. (a) On or before June 1 of each year, each insurer shall submit to the commissioner, on a form approved by the commissioner, a report describing clinical trials for which the insurer covered associated treatment cost during the prior year.

(b) The commissioner shall compile an annual summary report of the information submitted under subsection (a) and make copies available to the public.

(c) The commissioner shall adopt rules under IC 4-22-2 to implement this section.

SECTION 3. IC 27-13-7-15.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2001]: **Sec. 15.5. (a) As used in this section, "associated treatment cost" means the cost of a medically necessary treatment associated with clinical trial treatment. The term does not include:**

(1) the cost of an investigational drug or device used as part of the clinical trial treatment;

(2) the cost of nonhealth care services associated with the clinical trial treatment;

(3) the cost of managing the research associated with the clinical trial treatment; or

(4) a cost not covered under the health maintenance organization contract for noninvestigational treatments.

(b) As used in this section, "clinical trial treatment" means:

(1) treatment provided in a phase II, phase III, or phase IV clinical trial for a life threatening condition;

(2) prevention studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer;

(3) early detection studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer; or

(4) treatment studies in a phase I, phase II, phase III, or phase IV clinical trial for cancer;

that is approved by the National Institutes of Health or one (1) of its cooperative groups or centers, the federal Food and Drug Administration in the form of an investigational new drug application, the United States Department of Veterans Affairs, or an institutional review board of an institution in Indiana that has a multiple project assurance contract approved by the office of protection from research risks of the National Institutes of Health.

(c) As used in this section, "cooperative group" means a formal network of facilities that collaborate on research projects and have an established peer review program operating within the group that is approved by the National Institutes of Health. The term includes:

(1) the National Cancer Institute Clinical Cooperative Group;

(2) the National Cancer Institute Community Clinical Oncology Program;

(3) the AIDS Clinical Trials Group; and

(4) the community programs for clinical research in AIDS.

(d) As used in this section, "multiple project assurance contract" means a contract between an institution and the United

States Department of Health and Human Services that defines the relationship between the institution and the United States Department of Health and Human Services and specifies the responsibilities of the institution and procedures that will be used by the institution to protect human research subjects.

(e) A health maintenance organization issued a certificate of authority in Indiana shall provide coverage for associated treatment cost under an individual or group contract that provides coverage for basic health care services if:

(1) the facility and personnel providing the clinical trial treatment are approved by the organization sponsoring the clinical trial protocol and the institutional review board of the institution providing the clinical trial treatment;

(2) there is no clearly superior, noninvestigational treatment alternative to the clinical trial treatment; and

(3) the available clinical or preclinical data provide a reasonable expectation that the clinical trial treatment will be at least as effective as a noninvestigational alternative.

(f) The coverage required under subsection (e) includes associated treatment cost for a drug or device approved for sale by the federal Food and Drug Administration to the extent that the manufacturer, distributor or provider of the drug or device does not pay the cost, regardless of whether the drug or device is approved for the enrollee's particular condition.

(g) The coverage required by subsections (e) and (f) may not be subject to dollar limits, deductibles, copayments, or coinsurance provisions that are less favorable to an enrollee than the dollar limits, deductibles, copayments, or coinsurance provisions applying to physical illness generally under the health maintenance organization contract.

(h) On or before June 1 of each year, each health maintenance organization shall submit to the commissioner, on a form approved by the commissioner, a report describing clinical trials for which the health maintenance organization covered associated treatment cost during the prior year.

(i) The commissioner shall compile an annual summary report of the information gathered under subsection (h) and make copies available to the public.

(j) The commissioner shall adopt rules under IC 4-22-2 to implement subsections (h) and (i).

SECTION 4. [EFFECTIVE JULY 1, 2001] **(a) The work group on health care coverage for associated treatment cost is created to**

assess the costs and benefits of health care coverage by:

(1) state employee health benefit plans under IC 5-10-8-7.4, as added by this act;

(2) insurers under IC 27-8-14.3, as added by this act; and

(3) health maintenance organizations under IC 27-13-7-15.5, as added by this act;

for associated treatment cost as defined in IC 5-10-8-7.4, IC 27-8-14.3-1, and IC 27-13-7-15.5, all as added by this act.

(b) The work group on health care coverage for associated treatment cost consists of nine (9) members appointed by the insurance commissioner before January 1, 2002, as follows:

(1) One (1) member from the Indiana University School of Medicine.

(2) One (1) member from the Indiana State Medical Association.

(3) Two (2) representatives, including one (1) medical director licensed to practice medicine in Indiana, from accident and sickness insurers granted certificates of authority in Indiana.

(4) Two (2) representatives, including one (1) medical director licensed to practice medicine in Indiana, from health maintenance organizations granted certificates of authority in Indiana.

(5) One (1) member from the state personnel department.

(6) One (1) member of the public.

(7) The insurance commissioner, or the commissioner's designee.

(c) The insurance commissioner, or the commissioner's designee, shall serve as chairperson.

(d) Members shall serve until the final report is submitted under subsection (g).

(e) Each member of the work group who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). The member is also entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the Indiana department of administration and approved by the budget agency.

(f) The work group on health care coverage for associated treatment cost for clinical trials shall:

(1) develop a methodology for assessing the economic and clinical impact of the health care coverage required under IC 5-10-8-7.4, IC 27-8-14.3, and IC 27-13-7-15.5, all as added

by this act, for associated treatment cost;

(2) collect from health care providers and payers pertinent aggregate clinical and financial data on insured treatments to assess differences in associated treatment cost and clinical outcomes between insureds treated in clinical trials and insureds treated outside clinical trials;

(3) review any other issues the workgroup considers appropriate; and

(4) make recommendations to the insurance commissioner pertaining to coverage for associated treatment cost.

(g) The work group shall submit a final report, including findings and recommendations, to the legislative council on or before June 30, 2003.

(h) This SECTION expires June 30, 2006.

SECTION 5. [EFFECTIVE JULY 1, 2001] **(a) IC 5-10-8-7.4, as added by this act, applies to a self-insurance program or a contract with a prepaid health care delivery plan established, entered into, or renewed after June 30, 2001.**

(b) IC 27-8-14.3, as added by this act, applies to an accident and sickness insurance policy entered into, issued, delivered, or renewed after June 30, 2001.

(c) IC 27-13-7-15.5, as added by this act, applies to a health maintenance organization contract entered into, issued, delivered, or renewed after June 30, 2001.

(d) This SECTION expires June 30, 2007.